ACCOGENT

K101042

644 North Lake Way, Palm Beach, FL 33480

OCT 29 2010

510(k) Summary

Note: This is the "510(k) Summary" as required by section 807.92(c)

Accogent, LLC
510(k) Pre-market Notification; BladeView

Date: May 12th, 2010
Submitter's Name: Accogent, LLC
Submitter's Address: 644 North Lake Way
Palm Beach, FL
Submitter's Contact: Tristan Tice, Managing Member
Submitter's Telephone Number: (917) 513-7632
Submitter's Fax Number: (732) 747-6073

Establishment Registration Number: 3007230269

Device Name and Classification

Trade Name:	BladeView	CFR Section:	21 CFR § 892.1650
Classification Panel:	Radiology	Device Class:	Class II
Classification Name:	Solid State x-ray Imager (Flat Panel/Digital Imager)	Device Code:	MQB
Common Name:	Radiographic Digital Flat Panel Detector System		

Performance Standard: 21 CFR Subchapter J,
Federal Diagnostic X-ray Equipment Standard

Predicate Device Claiming Substantial Equivalence to: **CPI RAD VISION**
510(k) Control Number: K083224

Predicate Device Claiming Substantial Equivalence to: **HDR Vision**
510(k) Control Number: K081073

Reason For Submission New device

Description of this Device:
he BladeView is intended to be used as a universal diagnostic imaging system for radiographic studies.

ACCOGENT

The BladeView is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image. The main configuration includes a portable X-ray detector, generator, workstation and various other allied parts and components necessary for radiographic studies. It is also configurable to be used in an existing conventional radiographic room (Film or CR) and only the Flat panel and workstation would be needed.

The system has medical applications ranging from but not limited to cranial, skeletal, thoracic and lung exposures as well as examination of the extremities.

Summary of Intended Uses:
The BladeView is a full featured Radiographic Flat-Panel Digital Imaging System. It is intended to replace conventional film screen systems.

The BladeView allows a qualified operator to perform digital radiographic examinations of various anatomic regions on both adult and pediatric patients. Anatomic regions of interest for diagnostic radiographic exposure include: skull, spinal column, chest, shoulder girdle, abdomen, pelvic girdle and extremities.

The BladeView enables a qualified operator to acquire, process, and display images. The BladeView system enables the qualified operator to store, hardcopy images with a laser printer or send images over a network.

This device is not intended for mammographic, fluoroscopic and or angiographic applications.

Analysis of the Indications For Use for the Subject Device and Predicate Device(s):
Pursuant to §807.92(a)(5), this summary contains the following information as to why differences are not critical to the intended therapeutic, diagnostic, or surgical use of the device. In addition, this summary also contains an explanation why the differences do not affect the safety and effectiveness of the device.

A comparison of the subject device and the CPI RAD VISION (K093224) is as follows:

	CPI RAD VISION (K083224) PREDICATE DEVICE	BLADEVIEW SUBJECT DEVICE	EXPLANATION WHY DIFFERENCES ARE NOT CRITICAL TO USE OF THE DEVICE	WHY DIFFERENCES DO NOT AFFECT THE SAFETY AND EFFECTIVENESS OF THE DEVICE

ACCOGENT

	CPI RAD VISION (K083224) PREDICATE DEVICE	BLADEVIEW SUBJECT DEVICE	EXPLANATION WHY DIFFERENCES ARE NOT CRITICAL TO USE OF THE DEVICE	WHY DIFFERENCES DO NOT AFFECT THE SAFETY AND EFFECTIVENESS OF THE DEVICE
A1	The CPI RAD VISION is a full featured Radiographic Flat Panel Digital Imaging System for X-ray Generator and Acquisition of digital radiography.	The BladeView is a full featured Radiographic Flat-Panel Digital Imaging System.	The difference is not critical to the intended diagnostic use of the device. The difference is done to clear up any confusion or conflicts of interpretation.	The difference will not affect the safety and effectiveness of the device when used as labeled. The additional text is seen as being restatement of something that is implicit with the device as it is described in the Device Description Section.
A2	The CPI RAD VISION is configurable to any high resolution (3K x 3K) Solid State X-Ray Imager (SSXI) presently in the market.		The difference is not critical to the intended diagnostic use of the device. The difference is done because submitter does not wish to claim configurability as the intended diagnostic use will focused on its own Digital Flat Panel, and not the flat panel of our competitors.	The difference will not affect the safety and effectiveness of the device when used as labeled. This is exact claim that is difficult to support, however the Safety and effectiveness of the device (as well as its intended use) is not affected as the applicant's system will still ultimately have the same intended use (The generating of digital radiographic images of the human anatomy).
A3	It is intended to replace conventional film screen systems.	It is intended to replace conventional film screen systems.	There is no difference in the intended diagnostic use of the device.	There is no difference between both IFU's. Therefore there will be no affect in the safety and effectiveness of the device when used as labeled.

ACCOGENT

	CPI RAD VISION (K083224) PREDICATE DEVICE	BLADEVIEW SUBJECT DEVICE	EXPLANATION WHY DIFFERENCES ARE NOT CRITICAL TO USE OF THE DEVICE	WHY DIFFERENCES DO NOT AFFECT THE SAFETY AND EFFECTIVENESS OF THE DEVICE
B1	The CPI RAD VISION allows a qualified operator to perform digital radiographic examinations of various anatomic regions on both adult and pediatric patients.	The BladeView allows a qualified operator to perform digital radiographic examinations of various anatomic regions on both adult and pediatric patients.	There is no difference in the intended diagnostic use of the device.	There is no difference between both IFU's. Therefore there will be no affect in the safety and effectiveness of the device when used as labeled.
B2	Anatomic regions of interest for diagnostic radiographic exposure include: skull, spinal column, chest, shoulder girdle, abdomen, pelvic girdle and extremities.	Anatomic regions of interest for diagnostic radiographic exposure include: skull, spinal column, chest, shoulder girdle, abdomen, pelvic girdle and extremities.	There is no difference in the intended diagnostic use of the device.	There is no difference between both IFU's. Therefore there will be no affect in the safety and effectiveness of the device when used as labeled.

ACCOGENT

	CPI RAD VISION (K083224) PREDICATE DEVICE	BLADEVIEW SUBJECT DEVICE	EXPLANATION WHY DIFFERENCES ARE NOT CRITICAL TO USE OF THE DEVICE	WHY DIFFERENCES DO NOT AFFECT THE SAFETY AND EFFECTIVENESS OF THE DEVICE
C1	The CPI RAD VISION enables a qualified operator to acquire, process, and display images with for the benefit of obtaining an optimal diagnostic product.	The BladeView enables a qualified operator to acquire, process, and display images.	The first part is not different, however the second part is. The difference is not critical to the intended diagnostic use of the device. The difference is done because the predicate device's claim is difficult to support with quantitative data.	The difference will not affect the safety and effectiveness of the device when used as labeled. Both systems use the same detector from the same manufacturer. This detector provides an output image that is viewable already useable in its native format. This additional text that is not brought forward (excluding the "optimal" claim component) is seen as being restatement of something that is implicit with the device as it is a system being promulgated to obtain diagnostic images..
C2	The CPI RAD VISION system enables the qualified operator to store, hardcopy images with a laser printer or send images over a network.	The BladeView system enables the qualified operator to store, hardcopy images with a laser printer or send images over a network.	There is no difference in the intended diagnostic use of the device.	There is no difference between both IFU's. Therefore there will be no affect in the safety and effectiveness of the device when used as labeled.
C3	This device is not intended for mammographic, fluoroscopic and or angiographic applications.	This device is not intended for mammographic, fluoroscopic and or angiographic applications.	There is no difference in the intended diagnostic use of the device.	There is no difference between both IFU's. Therefore there will be no affect in the safety and effectiveness of the device when used as labeled.

ACCOGENT

	CPI RAD VISION (K083224) PREDICATE DEVICE	BLADEVIEW SUBJECT DEVICE	EXPLANATION WHY DIFFERENCES ARE NOT CRITICAL TO USE OF THE DEVICE	WHY DIFFERENCES DO NOT AFFECT THE SAFETY AND EFFECTIVENESS OF THE DEVICE
C4	The CPI RAD VISION will not include the X-Ray system itself.		The difference is not critical to the intended diagnostic use of the device. Specifically, the difference is done to clear up any confusion or conflicts of interpretation.	There is no difference that will affect the safety and effectiveness of the device when used as labeled.
D1	Device is for Prescription only	Device is for Prescription only	There is no difference in the intended diagnostic use of the device.	There is no difference between both IFU's. Therefore there will be no affect in the safety and effectiveness of the device when used as labeled.

ACCOGENT

A comparison of the subject device and the Pausch HDR Vision (K081073) is as follows:

	HDR Vision (K081073) Predicate Device	BladeView Subject Device	Explanation Why Differences are not Critical to Use of the Device	Why Differences do not Affect the Safety and Effectiveness of the Device
A 1	The HDR Vision is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies.	The BladeView is a full featured Radiographic Flat-Panel Digital Imaging System.	Applicant's system is intended for Radiographic examinations	The difference is not critical to the intended diagnostic use of the device because fluoroscopic examinations are not to be done with it.
A 2	Using a digital flat detector, it can perform a range of applications including general RIF, angiography and pediatric examinations.	The BladeView is a full featured Radiographic Flat-Panel Digital Imaging System.	Applicant's system is intended for Radiographic examinations	The difference is not critical to the intended diagnostic use of the device because fluoroscopic examinations are not to be done with it.
A 3	The HDR Vision is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image.	It is intended to replace conventional film screen systems.	Both passages are substantially similar, the difference is that the predicate device is explicit and the submission is implicit	There is no difference in the intended diagnostic use of the device.
B 1	The system has medical applications ranging from but not limited to gastrointestinal examinations, cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract.	The BladeView allows a qualified operator to perform digital radiographic examinations of various anatomic regions on both adult and pediatric patients.	Only conventional radiographic exposures apply. It is for these uses that device similarity between the two devices exist. However gastrointestinal examination and examinations of the urogenital tract are not found in the submission and therefore are not a claimed indication of use.	There is a difference in the intended diagnostic use of the device however, applicant is not including in its indications for use any incompatable procedures. To reiterate the differences are not critical to the applicant's device as it's intended diagnostic use is that of a Radiographic Flat-Panel Digital Imaging System.

ACCOGENT

	HDR Vision (K081073) Predicate Device	BladeView Subject Device	Explanation Why Differences are not Critical to Use of the Device	Why Differences do not Affect the Safety and Effectiveness of the Device
B2	The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography and digital subtraction angiography (DSA).	Anatomic regions of interest for diagnostic radiographic exposure include: skull, spinal column, chest, shoulder girdle, abdomen, pelvic girdle and extremities.	Only the conventional radiographic procedures applicable to the submission are brought forward. The other procedures are not claimed by the submitter therefore they are not included in submission's IFU.	The difference is not critical to the intended diagnostic use of the device because only conventional radiography are to be done with it. Any other uses would claimed need to be separately broken out and explicitly claimed. These additional procedures are not being done for the applicant's submitted device.
C1	HDR Vision may be used for outpatient and emergency treatment, as well as for mobile transport (wheelchair and bed) examinations.	The BladeView enables a qualified operator to acquire, process, and display images.	Applicant's system is intended for Radiographic examinations. While these are seen as being mostly conventional radiographic exposures they are not included in the applicant's IFU as it wanted to stay close to the IFU put for by CPI in its submission (K083224)	The difference is not critical to the intended diagnostic use of the device. Submission has not brought forward these items (bed & wheelchair) as they are commonplace in the modern US hospital environment all other submissions for digital radiographic devices do not feel the need to enumerate on these types of examinations.
C2		The BladeView system enables the qualified operator to store, hardcopy images with a laser printer or send images over a network.	Applicant's system is intended for Radiographic examinations. These functions are almost implicit with any modern digital radiographic system. This is included in the applicant's IFU as it wanted to stay close to the IFU put for by CPI in its submission (K083224)	There is no difference in the intended diagnostic use of the device as these features are inferred in the HDR Vision 510(k) summary in the Summary of Intended Uses Section where it states *"The system is used for image acquisition, image display, and the transmission/output of images to external devices."*

ACCOGENT

	HDR Vision (K081073) Predicate Device	BladeView Subject Device	Explanation Why Differences are not Critical to Use of the Device	Why Differences do not Affect the Safety and Effectiveness of the Device
C3		This device is not intended for mammographic, fluoroscopic and or angiographic applications.	Applicant's system is intended for Radiographic examinations. These functions are excluded by the applicant as. This is included in the applicant's IFU as it wanted to stay close to the IFU put for by CPI in its submission (K083224)	The difference is not critical to the intended diagnostic use of the device because only conventional radiography are to be done with it. Any other uses would claimed need to be separately broken out and explicitly claimed. These additional procedures (Fluoroscopy and angiographic applications) are not being done for the applicant's submitted device (Therefore they are not critical to the intended use of the device).
D1	Device is for Prescription only	Device is for Prescription only	Both passages are substantially similar.	There is no difference in the intended diagnostic use of the device with respect to this issue

Summary of Technological Characteristics for the Subject Device and Predicate Device(s):

Pursuant to §807.92(a)(6), this 510(k) summary contains the summary of the technological characteristics of the subject device compared to the predicate device(s). Where the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device, there is a summary of the technological characteristics of the new device in comparison to those of the predicate device. Where the subject device has different technological characteristics from the predicate device, a summary is provided of how the technological characteristics of subject device compare to the predicate device.

Summary of Technological Characteristics for the Subject Device and the CPI RAD VISION (K083224) Predicate Device:

Applicant submission of the required technical characteristics analysis is done using solely the information provided within the predicate device's (CPI's K083224) 510(k) Summary. This summary is as follows:

The technological characteristics are the same in the proposed and predicate devices. Both the predicate and new devices use x-rays received by Flat Panel Detector (acquisition) to create diagnostic images The detector converts the images into a digital form that can be viewed in a native format or state. Supplementary to the process it can be adjusted if necessary (processing), then stored locally (storage), sent to an archive, printed or sent to supported DICOM devices (distribution of images).

ACCOGENT

Summary of Technological Characteristics for the Subject Device and the Pausch VISION HDR (K081073) Predicate Device:

The following technological characteristics are the same in the proposed and predicate devices with respect to the following:

Both the predicate and new devices use x-rays received by Flat Panel Detector (acquisition)to create diagnostic images. The detector converts the images into a digital form that can be viewed in a native format or state. Supplementary to the process it can be adjusted if necessary (processing), then stored locally (storage), sent to an archive, printed or sent to supported DICOM devices (distribution of images).

The following technological characteristics are different in the proposed and predicate devices with respect to the following:

The submitted device does not perform fluoroscopy, nor does it use a Flat Panel Detector that is capable of performing Fluoroscopy. The predicate device has the technology to perform fluoroscopy, and it contains a Flat Panel Detector capable of doing Fluoroscopy. The submitted device is designed only to acquire and process radiographic images. The predicate device is designed to acquire and process radiographic images, fluoroscopic studies and numerous other procedures that submitted device is not qualified or otherwise intended to do.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Accogent LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K101042
Trade/Device Name: Blade View
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: September 24, 2010
Received: September 28, 2010

AUG 23 2013

Dear Mr. Job:

This letter corrects our substantially equivalent letter of October 29, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K101042

INDICATIONS FOR USE STATEMENT

OCT 29 2010

INDICATIONS FOR USE

510(k) Number: K101042

Device Name: BladeView

Indications For Use:

The BladeView is a full featured Radiographic Flat-Panel Digital Imaging System. It is intended to replace conventional film screen systems.

The BladeView allows a qualified operator to perform digital radiographic examinations of various anatomic regions on both adult and pediatric patients. Anatomic regions of interest for diagnostic radiographic exposure include: skull, spinal column, chest, shoulder girdle, abdomen, pelvic girdle and extremities.

The BladeView enables a qualified operator to acquire, process, and display images. The BladeView system enables the qualified operator to store, hardcopy images with a laser printer or send images over a network.

This device is not intended for mammographic, fluoroscopic and or angiographic applications.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

10/29/10